



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1020

[Docket No. FDA-2015-N-0828]

Performance Standards for Ionizing Radiation Emitting Products; Fluoroscopic Equipment;
Correction; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is confirming the effective date of August 26, 2015, for the direct final rule that appeared in the Federal Register of April 13, 2015. The direct final rule amends a Federal performance standard for ionizing radiation to correct a drafting error regarding fluoroscopic equipment measurement. We are taking this action to ensure clarity and improve the accuracy of the regulations. This document confirms the effective date of the direct final rule.

DATES: Effective date of the final rule published in the Federal Register of April 13, 2015 (80 FR 19530), confirmed: August 26, 2015.

FOR FURTHER INFORMATION CONTACT: Scott Gonzalez, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4641, Silver Spring, MD 20993-0002, 301-796-5889.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 13, 2015 (80 FR 19530), FDA solicited comments concerning the direct final rule for a 75-day period ending June 29, 2015. We stated that the effective date of the direct final rule would be on August 26, 2015, 30 days after the end of the comment period, unless FDA received any significant adverse comment during the comment period. FDA did not receive any significant adverse comments.

Authority: 21 U.S.C. 351, 352, 360e-360j, 360hh-360ss, 371, 381. Accordingly, the amendment issued thereby is effective.

Dated: July 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-17930 Filed: 7/21/2015 08:45 am; Publication Date: 7/22/2015]